Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0648262	01/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hospital District #1 Of Crawford County	302 N Hospital Drive, Girard, KS	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of quality control (QC) records, and interview with the general supervisor (GS)#1, the laboratory failed check each lot number and new shipment of catalase and optochin for positive and negative reactivity prior to use for patient testing. Findings: 1. Review of the QC records for catalase revealed no QC testing had been performed since 9/2020. Exact date not available. 2. Review of the QC records for Optochin revealed no QC testing had been performed since 7/2/2021. 3. The current reagent for catalase testing was not made available at the time of survey. 4. Examination of new Optochin reagent revealed an open date of 6/8/2022. 5. Interview with GS#1 on 1/25/23 at 9:50 a.m. confirmed, the laboratory failed check each lot number and new shipment of catalase and optochin for positive and negative reactivity prior to use for patient testing.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains.

	This STANDARD is not met as evidenced by: Based on the review of gram stain QC records and interview with GS#1, the laboratory failed to check gram stain for positive and negative reactivity with control organisms each week prior to use for patient testing. 1. Review of the form "GRAM STAIN QC" revealed QC was performed using organisms of known reactivity, but at irregular intervals that exceeded 7 days 29 out of 57 weeks. 2. From 12/14/21 to 1/25 /23, QC was performed as follows for each month: a. 12/21-performed 12/14/21 and 12/26/21. b. 1/22- performed 1/24/22 c. 2/22-performed 2/1/22, 2/14/22, and 2/21/22 d. 3/22-performed 3/7/22, 3/15/22 e. 4/22-performed 4/6/22, 4/22/22 and 4/29/22 f. 5 /22-performed 5/6/22, 5/13/22 and 5/20/22. g. 6/22-performed 6/13/22 and 6/20/22 h. 7/22-performed 7/5/22 and 7/25/22 i. 8/22-performed 8/8/22 and 8/31/22 j. 9/22-performed 9/9/22, 9/13/22, 9/27/22 and 9/29/22 k. 10/22-performed 10/10/22, 10/17 /22 l. 11/22-no documentation of QC for this month was provided at the time of survey m. 12/22-no documentation of QC for this month was provided at the time of survey o. 1/23-performed 1/2/23 and 1/15/23 2. No documentation of "no patient testing performed" for lack of QC testing was found on the QC logs. No documentation of review or corrective actions for failure to perform QC as required was made available at the time of survey. 3. Interview with GS#1 1/25/23 at 9:50 a.m. confirmed, the laboratory failed to check gram stain for positive and negative reactivity with control organisms each week prior to use for patient testing for 28 of 57 weeks.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and calibration records for AST and Lactic Acid performed on the Abbott Architect chemistry analyzer S/N 68550 from 12 /26/22 to 1/23/23, lack of patient remediation documentation for AST and Lactic patient results and interview with GS #1, the laboratory failed to evaluate patient test results since the last acceptable QC test run to determine if patient results had been adversely affected and may require corrective action. Findings: 1. Review of AST QC records and AST calibration records from the Abbott Architect revealed unacceptable QC values that required calibration in order to obtain acceptable QC values post calibration on 1/5/23. Unacceptable QC was also found on 1/6/23 through 1/9/23 with calibrations performed 1/6/23, two calibrations on 1/7/23 and two calibrations on 1/9 /23. Acceptable QC was not attained until after the second calibration on 1/9/23. Evaluation of prior AST patient results from 1/5/23 to 1/9/23 for possible corrective action was not provided on the date of survey. No documentation to demonstrate AST patient testing was not performed from 1/5/23 to 1/9/23 was provided on the date of survey. No corrective action documentation was present including notification to the provider and patients of results, and orientation/training for the performing test personnel was provided at the time of survey. 2. Review of Lactic Acid QC records

	and Lactic Acid calibration records from the Abbott Architect revealed unacceptable QC values that required calibration in order to obtain acceptable QC values post calibration on 1/2/23, 1/5/23, 1/9/23, 1/21/23 and 1/23/23. 3. Further review of Lactic Acid QC results revealed unacceptable QC values with no acceptable values after repeat testing on 12/26/22, 1/3/23, 1/4/23, 1/14/23, 1/15/23, and 1/18/23. 4. No documentation for all dates listed in items #2 and #3 to demonstrate Lactic Acid patient testing was not performed or results were evaluated for possible corrective action was provided at the time of survey. No corrective action documentation was present including notification to the provider and patients of results, and orientation /training for the performing test personnel was provided at the time of survey. 5. Review of patient test results revealed 136 AST results and 5 Lactic Acid results were reported without evaluation for the unacceptable QC and calibrations. 6. Interview with GS #1 1/25/23 at 2:15 p.m. confirmed, the laboratory failed to evaluate AST and Lactic Acid patient test results since the last acceptable test run to determine if patient results had been adversely affected and may require corrective action.
D6148	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4) The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained. This STANDARD is not met as evidenced by: Based on the lack of review documentation of microbiology QC, Abbott chemistry QC and calibrations, iSTAT blood gas QC, failure to perform patient look back and corrective actions for unacceptable Abbott analyzer calibrations and QC, and interview, the general supervisor failed to ensure that acceptable levels of analytic performance were maintained. Findings: 1. Review of microbiology QC revealed no general supervisor (GS) review documentation for 2022. Optochin and gram stain QC were not performed as required. No corrective action documentation was made available at the time of survey. (refer to D5471 and D5503) 2. Review of chemistry calibrations and QC for the Abbott chemistry analyzer and QC for the iSTAT chemistry analyzer revealed no GS review documentation for 2022. Abbott analyzer showed multiple dates of unacceptable QC and calibrations. No corrective action documentation was made available at the time of survey. (refer to D5783) 3. Interview with GS #1 on 1/25/23 at 3:25 p.m. confirmed, the general supervisor failed to ensure that acceptable levels of analytic performance were maintained.